VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/12/09

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Kathleen Boland, Pharm.D.
Lynne Vezina, R.Ph.
Richard Harvie, R. Ph.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Nancy Miner, (MHP)
Stacey Baker, OVHA
Cynthia LaWare, OVHA
Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA
Judy Jamieson, OVHA

Guests:

Sam Davis, BMS
Michael Deorsey, Abbott
Glenn E. Dooley, Sr, Sanofi-Aventis
Craig Gill, Pfizer
Brian Korenda, GSK
Chris Michaud, Elan
Danielle Moon, Merck
Carl Possidente, Pfizer
Pam Salisbury, Lundbeck
Emil Swift, Bristol-Myers Squibb
Keith White, Genentech
Joe Winalski, Biogen Idec

Michael Scovner, M.D. Chair, called the meeting to order at 7:03 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The March 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Suit re: Act 80: The State did prevail in the suit brought by Pharma. An educational based detailing program and a generic voucher program can now begin.
- Legislative Report: The budget bill has passed the legislature but may be vetoed. There are a number of items specific to the pharmacy program. These include a 90 day mandatory dispensing of maintenance medications, a reduction in out-of-state dispensing fees, a reduction in reimbursement to pharmacies, copayments in VHAP and VPharm for certain members, generic coverage in certain drug categories for VPharm and rebate requirements in VPharm.

4. Medical Director Update: Medical Director Absent

- Clinical Programs Update: No items to report.

- Prescriber Comments: No comments to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Nplate® (romiplostim) – deferred until next meeting in order to obtain comments from a hematologist.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Durezol® (difluprednate) Ophthalmic: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient must have a documented inadequate response, adverse reaction, or contraindication to at least one generic ophthalmic topical corticosteroid.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Requip XL® (ropinirole) Extended Release Tablet (abbreviated review): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication is Parkinson's disease AND the patient has had an inadequate response (i.e., wearing off effect or "off" time) with the generic ropinirole/Requip® IR OR the patient has not been able to be adherent to a three times daily dosing schedule of ropinirole/Requip® IR resulting in a significant clinical impact. Additionally, it was recommended that Requip XL® not be approved for treatment of restless leg syndrome (RLS).

Public Comment: Brian Korenda, GSK – Commented on the advantages of once daily dosing with Requip XL® and its efficacy compared to placebo.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Sancuso® (granisetron) Transdermal System: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis is nausea and vomiting associated with cancer chemotherapy AND there is documentation of medical necessity for the transdermal formulation OR the patient has had a documented side effect, allergy or treatment failure with generic ondansetron. A quantity limit of 1 patch per course of chemotherapy is recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Xenazine® (tetrabenazine) Tablet: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient age ≥ 18 AND there is a documented diagnosis of Huntington's disease with chorea. The initial approval would be for a maximum of 50 mg/day.

Public Comment: *Pam Salisbury, Lundbeck* – Commented on the use in tardive dyskinesia.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Atypical Antipsychotics (in Major Depressive Disorder):
A variety of atypical antipsychotics have been studied in the treatment of major depressive disorder after failure of first and second line therapies. Abilify® is the only atypical antipsychotic FDA approved for use as an adjunctive treatment in MDD in adults. An application has been submitted to the FDA for Seroquel XR® in MDD. It was recommended that the current clinical criteria for non-preferred atypical antipsychotics remain as is; that is, the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR the patient has had a documented side effect, allergy or treatment failure with at least two preferred products.

Public Comment: Emil Swift, Bristol-Myers Squibb – Commented on the efficacy of Abilify® in MDD.

Board Decision: The DUR Board voted to establish a separate criterion for atypical antipsychotics for use in MDD with criteria for approval of non-preferred products being the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR the patient has had a documented side effect, allergy or treatment failure with one preferred product.

- Glucocorticoids: Topical:
The table of topical glucocorticoids was updated to include all products and dosage forms in the 4 potency categories. No changes to the clinical criteria for non-preferred products are recommended.

Public Comment: No public comment.

Board Decision: The Board approved the updated table of products.

- New to Market Drugs:
It was recommended that an additional criterion be added for requests for new to market drugs when the request is for an off-label use. The request would need to be sent to OVHA (from the Clinical Call Center) and the prescriber would need to provide peer reviewed medical literature to support the off-label use.

Public Comment: No public comment.

Board Decision: The DUR Board approved the addition of the above criterion for new to market drugs when requested for off-label use.

8. **Drug Classes – Annual Review:**
(Public comment prior to Board action)

Analgesics

- Cyclooxygenase-2 (COX-2) Inhibitors - No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria unchanged.

- Nonsteroidal Anti-Inflammatory Drugs (NSAID) – It was recommended that oral ketorolac be moved to preferred status with the quantity limit changed to 20 doses per 90 days. No other changes recommended.

Public Comment: No public comment.

Board Decision: The Board approved the change above as recommended by MHP.

Narcotics-Short Acting – No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

Chemical Dependency

- Buprenorphine and Buprenorphine/naloxone – It was recommended that if requesting Subutex®, the allergic reaction must be witnessed by a healthcare professional (to prevent self declared allergic reactions). Quantity limits of 3 tablets per day for both products and at all tablet strengths was recommended to encourage dose consolidation as well as maximum doses within the 16 – 24 mg/day range.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Naltrexone for Opioid Detox - No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

9. <u>RetroDUR:</u> *Diane Neal, R.Ph, (MHP)*

- <u>Vivitrol®</u>: Utilization data along with prior authorization requests were evaluated from December 1, 2007 to February 28, 2009. The results showed an overall stable utilization of the medication within the specified time period. From December 1, 2007 to February 28, 2009, there were 23 unique utilizers of Vivitrol®, resulting in 64 paid claims, costing $49,212.68. This QA analysis demonstrates that Vivitrol® has a high rate of appropriate utilization. However, due to the high cost of the medication, and the potential risk of inappropriate prescribing, specifically the use of this medication in non-alcohol addiction, it is recommended that Vivitrol® continue to require prior authorization. Furthermore, it is also recommended that any requests that exceed the 6-month duration limit be forwarded to the OVHA medical director where they will be evaluated on a case-by-case basis.

Public Comment: No public comment.

Board Decision: None needed.

10. New Drug Product Plan Exclusions (Consent Agenda Topic): *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 03/06/09 - 04/24/09. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log (Consent Agenda Topic): *Diane Neal, R.Ph, (MHP)*

- It was proposed that the log be posted on the web site going forward as well as sent to the DUR Board members on their packet CD. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: The Board approved posting the log on the web rather than discussing at the meeting.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*
FDA Safety Alerts

- No reports to discuss this month

13. Adjourn: Meeting adjourned at 8:47 p.m.

Next DUR Board Meeting
Tuesday, June 09, 2009
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.